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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/979,549	05/12/2003	Marie-Francoise Gautier	ORES10.001APC	5002

20995 7590 01/05/2006

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/979,549

Applicant(s)

GAUTIER ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1101.0502.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Specification*

The specification is objected to because it does not contain reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74. See MPEP § 608.01(f).

### *Claim Rejections - 35 USC § 112 and 101*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a promoter comprising a nucleic acid fragment comprising at least one specific functional domain of the promoter of the TaTrxh2 gene, including a fragment wherein the sequence extends from position -1 to position -1111 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -1 to position -83 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -451 to position -591 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -591 to position -1111 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -228 to position -451 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -451 to position -591

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relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -83 to position -228 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence is that of the first intron of the TaTrxh2 gene. The claims are also drawn to an expression cassette, a recombinant vector, a transformed plant cell, a transgenic plant including a monocotyledonous plant, and a method for controlling the expression of a gene of interest in a plant cell.

The specification describes the TaTrxh2 gene as encoding a soft wheat (*Triticum aestivum*) thioredoxin h protein, the sequence of said gene and of the region in 5' comprising the promoter are represented in the attached sequence listing under the number SEQ ID NO: 1 (pages 2-3). The specification describes the 5' non-coding region (promoter) of TaTrxh2 gene as comprising the nucleic acid fragment which is represented in the attached sequence listing by the sequence SEQ ID NO: 2, and which is also represented in Figure 1, and which extends from position -1 to position -1111 relative to the ATG initiation codon of the TaTrxh2 (page 3). The specification describes specific structural components of the 5' non-coding region (promoter) of TaTrxh2 gene at pages 9-12, and the specification describes the functional characterization of the 5' non-coding region (promoter) of TaTrxh2 gene and four specific truncations (fragments) thereof at pages 12-20. The specification does not describe other sequences that are designated as "TaTrxh2", or as "TaTrxh2" promoter sequences.

The Federal Circuit has recently clarified the application of the written description requirement to nucleotide sequences. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University*

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*of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

The court has also stated that "a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA.

*See Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606.

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus which encompasses promoter sequences designated "TaTrxh2", nor the structural features unique to the genus. Applicant also has not defined the type of promoter being claimed by its structure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 provides for the use of the promoter of Claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Brugidou C. et al.

(The *Nicotiana tabacum* genome encodes two cytoplasmic thioredoxin genes which are differently expressed. Mol Gen Genet. 1993 Apr;238(1-2):285-93).

The claims are drawn to a promoter comprising a nucleic acid fragment comprising at least one specific functional domain of the promoter of the TaTrxh2 gene, including a fragment wherein the sequence extends from position -1 to position -1111 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -1 to position -83 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -451 to position -591 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -591 to position -1111 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -228 to position -451 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -451 to position -591 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -83 to position -228 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence is that of the first intron of the TaTrxh2 gene. The claims are also drawn to an expression cassette and a recombinant vector.

Brugidou C. et al. teach a promoter comprising a nucleic acid fragment comprising at least one specific functional domain of the promoter of the *Nicotiana tabacum* thioredoxin h gene,

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including fragments relative to the ATG codon and a first intron (page 288 Figure 2). Brugidou C. et al. also teach an expression cassette and a recombinant vector (page 286 column 2; page 288 Figure 2). The promoter taught by Brugidou C. et al. comprises at least one functional domain of the disclosed TaTrxh2 gene promoter (GC box, A sequence rich in adenine; see page 10 of the specification). Additionally, while Brugidou C. do not explicitly teach that their promoter is "of the TaTrxh2 gene", Brugidou C. need not teach this limitation in order to anticipate the rejected claims, as a name imposes no specific structural limitations on the claimed promoter sequences.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brugidou C. et al. (The *Nicotiana tabacum* genome encodes two cytoplasmic thioredoxin genes which are differently expressed. Mol Gen Genet. 1993 Apr;238(1-2):285-93) in view of Cornejo M.J. et al. (Activity of a maize ubiquitin promoter in transgenic rice. Plant Mol Biol. 1993 Nov;23(3):567-81).

The claims are drawn to a promoter comprising a nucleic acid fragment comprising at least one specific functional domain of the promoter of the TaTrxh2 gene, including a fragment wherein the sequence extends from position -1 to position -1111 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -1 to position -83 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -451 to position

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-591 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -591 to position -1111 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -228 to position -451 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -451 to position -591 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence extends from position -83 to position -228 relative to the ATG codon of the TaTrxh2 gene; a fragment wherein the sequence is that of the first intron of the TaTrxh2 gene. The claims are also drawn to an expression cassette, a recombinant vector, a transformed plant cell, a transgenic plant including a monocotyledonous plant, and a method for controlling the expression of a gene of interest in a plant cell.

The teachings of Brugidou C. et al. are set forth above. Brugidou C. et al. also teach that expression of the *Nicotiana tabacum* thioredoxin h gene is detectable in all young tissues that contain dividing cells (page 290 column 2 and Fig. 6A).

Brugidou C. et al. do not teach a transformed plant cell, a transgenic plant including a monocotyledonous plant, or a method for controlling the expression of a gene of interest in a plant cell.

Cornejo M.J. et al. teach the use of the maize ubiquitin 1 promoter, first exon and first intron (UBI) for rice (*Oryza sativa* L. cv. Taipei 309) transformation experiments, and its expression in transgenic calli and plants (abstract). Cornejo M.J. et al. also identified stable transformants obtained from callus-derived protoplasts co-transfected with two chimeric genes, the genes consisting of UBI fused to the coding regions of the uidA and bar marker genes (UBI:GUS and UBI:BAR) (page 575 Figure 5). Cornejo M.J. et al. additionally teach that histochemical



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localization of GUS activity revealed that UBI was most active in rapidly dividing cells (abstract; page 576 Figure 6).

Given the teachings of Brugidou C. et al. that expression of the *Nicotiana tabacum* thioredoxin h gene is detectable in all young tissues that contain dividing cells, and given the teachings of Cornejo M.J. et al. that a promoter sequence obtained from a gene expressed in dividing cells can be further characterized by using that sequence to control the expression of a reporter gene of interest in a plant cell or plant transformed therewith, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to further characterize the *Nicotiana tabacum* thioredoxin h gene promoter sequence taught by Brugidou C. et al. by using that sequence to control the expression of a reporter gene of interest in a plant cell or plant transformed therewith as taught by Cornejo M.J. et al. One skilled in the art would have been motivated to do so in order to confirm the specific functional characteristics of the *Nicotiana tabacum* thioredoxin h gene promoter sequence. One skilled in the art would have had a reasonable expectation of success in view of the identification of specific functional motifs in the *Nicotiana tabacum* thioredoxin h gene promoter sequence, and in view of the general state of the art with respect to the functional characterization of promoter sequences as exemplified by Cornejo M.J. et al. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

#### **Remarks**

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins  
Primary Examiner  
Art Unit 1638

CC

  
9/1/05